



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License:** Use of the Citrus Flavanones Hesperetin, Hesperidin, and Naringenin in Nutrition for Endothelial Function, Vascular Health, Diabetes, and Insulin Resistance

**AGENCY:** National Institutes of Health, Public Health Service, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to BioActor B.V., a company having a place of business in Maastricht, Netherlands, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/369,229, filed July 30, 2010 (HHS Ref. No. E-148-2010/0-US-01) and PCT Patent Application No. PCT/US2011/045898, filed July 29, 2011 (HHS Ref. No. E-148-2010/0-PCT-02), both entitled “Treatment of Metabolic Syndrome and Insulin Resistance with Citrus Flavanones.” The patent rights in these inventions have been assigned to the United States of America. The prospective exclusive license territory may be “worldwide”, and the field of use may be limited to “hesperidin, naringenin, and any derivatives thereof for

use in nutrition relating to endothelial function, vascular health, diabetes, and insulin resistance, wherein the Licensed Products are marketed under an approved Health Claim or GRAS designation from the FDA, under an approved Health Claim or Novel Food designation from the EFSA, or a foreign regulatory equivalent of the above.”

**DATE:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**FOR FURTHER INFORMATION:** Requests for copies of the patent application(s), inquiries, and comments relating to the contemplated exclusive license should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4426; Facsimile: (301) 402-0220; E-mail: [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** Hesperidin is a flavonoid compound found in citrus fruits. Large epidemiological studies have linked increased consumption of flavonoid-rich foods, such as citrus, with reduced cardiovascular morbidity and mortality. Investigators from the National Center for Complementary and Alternative Medicine have demonstrated that administration of oral hesperidin to patients with metabolic syndrome attenuates biomarkers of inflammation and improves blood vessel relaxation, lipid cholesterol profiles, and insulin sensitivity when compared to controls. Thus,

hesperidin and its active aglycone form, hesperetin, may be effective agents for the treatment of diabetes, obesity, metabolic syndrome, dyslipidemias, and their cardiovascular complications including hypertension, atherosclerosis, coronary heart disease, and stroke. This technology discloses methods for using a hesperetin or hesperidin composition to treat metabolic syndrome and insulin resistance. Also described is the use of the related citrus polyphenol, naringenin.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Only applications for a license in the field of use set forth in this notice and filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

June 29, 2012  
Date

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Richard U. Rodriguez,  
Director  
Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

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